Drawing Amendments

Please enter the attached amended drawings. As requested by the Examiner, Applicants have added "Prior Art" labels to FIG. 1 and FIG 2. Replacement drawing sheets and annotated drawing sheets are attached hereto.

REMARKS

Status of Claims

Claims 18-28 and 43-45 were pending at the time of the Office Action and claims 29-42 and 46-47 were previously withdrawn in a Response to Restriction Requirement filed 12/13/2010. Claims 29-42 and 46-47 have now been cancelled without prejudice or disclaimer. Applicants reserve the right to pursue the cancelled claims in one or more divisional or continuation application. Claims 21, 25 and 43 have been amended herein. Amendments are supported by the originally filed specification, claims and drawings. No new matter is introduced by these amendments. Accordingly, claims 18-28 and 43-45 are now pending.

Amendment to Drawings

In accordance to the Examiner's request Applicants present herewith amended drawings with the caption "prior art" added to FIG 1 and 2. No new matter is added by this amendment as these embodiments are described at least in the published specification at [0004]-[0006].

Rejections Under 35 U.S.C. § 112

The Examiner has rejected claims 18-28 and 43-45 under 35 U.S.C. § 112, second ¶, for being indefinite. Applicants respectfully traverse and address each of the Examiner's rejections in sections below:

1. The Examiner has rejected claims 18 and 25 under 35 U.S.C. § 112, sixth ¶, for reciting "pressure maintaining means" which the Examiner alleges is a means plus function limitation and says that "the written description fails to clearly link or associate the disclosed structure, material or acts to the claimed function such that one of ordinary skill in the art would recognize what structure, material or acts perform the claimed function.

Applicants respectfully traverse the § 112, sixth ¶, rejections and submit that several structural components that may be "pressure maintaining means" are adequately described in the specification as originally filed, see for example at least the following sections of the published application including: [0013], [0021], [0022], [0024], [0060] and FID. 4, [0061] and

FIG. 5, [0062] and FIG 6, [0063] and FIG. 7, [0064] and FIG 8, [0065] and FIG 9, [0066] and FIG 13, [0080], [0083], [0099], and original claims 24 and 26, all of which describe and illustrate a variety of structural embodiments described by this term in sufficient detail as would be required by one of skill in the art. Accordingly, Applicants respectfully submit that claims 18 and 25 do not to invoke 35 U.S.C. § 112, sixth ¶, rejections (or 35 U.S.C. § 112, second ¶, rejections for analogous reasons) and respectfully request withdrawal of the instant rejections.

2. Claims 21 and 25 are rejected for lacking antecedent basis for the term "the electrode." Applicants respectfully traverse and present amended claims 21 and 25 that are now free of the antecedent basis issues and respectfully request withdrawal of the instant rejections.

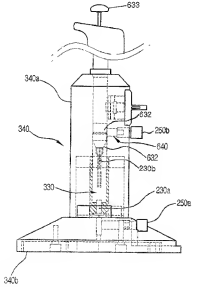
3. Claim 25 has been rejected as being indefinite for reciting "an electrode terminal for electrically connecting the fixing unit" and alleged that it is not clear how the fixing unit participates in generation of electrical pulses. Applicants respectfully traverse the indefiniteness rejection. It is not clear to Applicants why the Examiner is enquiring about the fixing unit participating in generation of electrical pulse. Claim 25 does not recite that the fixing unit participates in generation of electrical pulse.

However, the element above, *i.e.,* "an electrode terminal for electrically connecting the fixing unit" is well supported in the specification and Applicants request the Examiner to kindly review at least and the published specification at original claim 45, [0014], [0022], FIG. 12 and [0066] all of which describe elements of claim 25 and their function. For example, [0066] and FIG. 12 are reproduced below, for the convenience of the Examiner, which recite:

> [0066] FIG. 12 illustrates a structure of a reservoir (330) and a reservoir holder (340) used for the electroporation apparatus according to the present invention. The **reservoir holder (340) is formed at an upper inner pipe wall with a pipette fixing unit (640) for fixing the pipette, and is also disposed with an electrode terminal (250b) for electrically connecting to the fixing unit (640) and the other electrode terminal (250a) formed at a floor thereof**. The reservoir is mounted thereunder with an electrode (230a) for contacting the electrolytic solution or specimen. **If the pipette (630) is fixed at the pipette fixing unit (640) of the reservoir holder, the movable electrode (230b), the**

pipette contact (632) and the pipette fixing unit (640) are electrically connected. In conducting the electroporation, the specimen is picked by a pipette and stuffed in the specimen-stuffing member (440), the reservoir (330) filled with electrolytic solution is inserted into an inner pipe of the reservoir holder (340), the pipette is fixedly inserted into the pipette fixing unit (640) to allow a distal end of the pipette to fluidly communicate with the electrolytic solution of the reservoir, and electric pulse is applied to the two electrodes (230a, 230b) via the electrode terminals (250a, 250b) of the reservoir holder (340) to enable to electroporate the cell in the specimen-stuffing member. After the electroporation, the pipette is separated from the reservoir and the reservoir holder, and a pipette press button (633) is depressed to enable to easily retrieve the electroporated cell. The reservoir holder (340) may be so manufactured as to be separable between an upper lid (340a) and a body (340b) (see FIG. 12), or may be integrally manufactured. The specimen-stuffing member is detachably connected to the pipette tip mounting shaft (631) such that it may be disposably manufactured (see FIG. 10). Furthermore, an automatic electroporation system can be provided using the said electroporation apparatus and the electric pulse generator. FIG. 13 illustrates another embodiment of an electroporation system according to the present invention in which one or more electroporation apparatuses each including a specimen-stuffing member connected to a syringe-type pressure maintaining means are arranged in parallel.

([0066] of present specification, **emphasis added**)



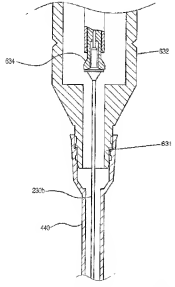
(FIG 12 of present specification)

In light of the above, Applicants respectfully submit that claim 25 is not indefinite under 35 U.S.C. § 112, second ¶, and respectfully request withdrawal of the instant rejection.

4. With respect to claim 26 the Examiner has enquired how (and if) the "conductive contact" structurally cooperates with "an electrode terminal."

Applicants kindly refer to Examiner to at least FIG. 9, FIG 10, FIGS 11A and 11B, and [0065] of the published specification which describe the structure of claimed embodiments of claim 26 and recites:

> [0065] FIG. 9 illustrates a structure of a pipette used for an electroporation apparatus according to the present invention, wherein the pipette (630) is used as a pressure maintaining means for fluidly communicating with the specimen-stuffing member. FIG10 illustrates a partially enlarged view of the pipette (630) connected to a movable electrode (230b) and a specimen-stuffing member (440). The specimen-stuffing member (440) is directly connected to a pipette tip mounting shaft (631). The **pipette (630) used as a pressure maintaining means is disposed at a body thereof with a conductive contact (632), and a movable electrode (230b) is inserted into the specimen-stuffing member and mounted in the pipette so as to communicate with a piston (634) in the pepette and to reciprocate in the specimen-stuffing member**. FIGS. 11(a) and (b) illustrate a specimen-stuffing member (440) and a movable electrode (230b) used for the pipette.



([0065] and FIG 10 of the present specification, **emphasis added**)

In light of the above, Applicants respectfully submit that claim 26 is not indefinite under 35 U.S.C. § 112, second ¶, and respectfully request withdrawal of the instant rejections.

5. Claim 43 has been rejected as lacking antecedent basis. Applicants have amended claim 43 to now recite "another electrode" and "an electrode insertion unit" to overcome the antecedent basis rejections. In light of these amendments, Applicants respectfully submit that claim 43, as amended, is not indefinite under 35 U.S.C. § 112, second ¶, and respectfully request withdrawal of the instant rejections.

Applicants submit that claims 19, 20, 22-24, 27, 28, 44 and 45 are also now free of the rejections of indefiniteness since their independent claims are now believed to be free of the indefiniteness rejections for reasons provided above. Accordingly, Applicants respectfully request withdrawal of the 35 U.S.C. § 112, second ¶, rejections (and sixth paragraph rejections) and request allowance of claims 18-28 and 43-45.

Rejections Under 35 U.S.C. § 102

The Examiner has rejected claims 18-25, 27, 28 and 43 under 35 U.S.C. § 102(b) as being anticipated by Preece et al., (EP 0 338 667, referred to hereinafter as "Preece") citing a variety of reasons on pages 5 and 6 of the present Office Action.

Applicants respectfully traverse the rejections and note that the Manual of the Patent Examining Procedure (MPEP) in §2131 provides the requirements for establishing anticipation and states "A claim is anticipated only if **each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference**." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The **identical invention must be shown in as complete detail as is contained in the .... claim**." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). "The **elements must be arranged as required by the claim**,....." *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990). (**emphasis added**).

According to the current laws, to anticipate claims 18-25, 27, 28 and 43 under 35 U.S.C. § 102 (b), Preece must teach "each and every element" of the claimed invention and "elements must be arranged as required by the claim." Applicants have reviewed the Examiner's rejections and sections recited in the Office Action and submit that Preece does not anticipate currently amended independent claims 18 and 25 and their dependents claims 19-24, 27, 28 and 43 since Preece fails to teach "each and every element" of these claims and it further fails to teach "the identical invention" of the currently claimed embodiments.

For example, Preece fails to teach or suggest at least the following elements of independent claims 18 and 25 including: "an electroporation apparatus" and instead appear to describe a "cell fusion apparatus and more particularly to apparatus for fusing cells by electrofusion, for example to produce hybridomas" as recited in the section titled "Field of Invention" and also "apparatus for the electrofusion of cells" as recited in claim 1 of Preece. The apparatus of Preece is not intended for the same purpose as Applicants apparatus's claimed in claims 18 and 25 and their dependents.

In addition Preece fails to teach at least the following elements of claim 18 including: "an electroporation apparatus for applying an electric pulse or electric pulses to a specimen including cells to thereby electroporate cell membranes and infuse foreign materials into the cells;" "a long hollow specimen-stuffing member of non-conductive material;" "a reservoir connected to a distal end of the specimen-stuffing member for fluid communication;" and "a pressure maintaining means connected to the other distal end of the specimen-stuffing member for fluid communication."

Preece also fails to teach at least the following elements of independent claim 25 including: "electroporation apparatus for applying an electric pulse or electric pulses to a specimen including cells to thereby electroporate cell membranes and infuse foreign materials into the cells;" "comprising: a long hollow specimen-stuffing member of non-conductive material;" "a pressure maintaining means connected to a distal end of the specimen-stuffing member for fluid communication;" "a reservoir connected to the other distal end of the specimen-stuffing member for fluid communication and disposed with an electrode for contacting the specimen or an electrolytic solution;" and "a reservoir holder including a fixing unit for fixing the pressure maintaining means, an electrode terminal for electrically connecting

the fixing unit and an electrode terminal for electrically connecting the electrode disposed at the reservoir."

For example, Applicants have noted that Examiner has equated part 14 of Preece's FIG 1 with current claims 18 (and 25) "specimen- stuffing member", and parts 24, 32 of Preece as "reservoir" of claims 18 (and 25). Applicants respectfully traverse.

First part 24 of Preece is described as "inlet/outlet passages 22, 24" (see Preece, column 3, lines 1-3) and part 32 of Preece is described as "a disposable outlet tip 32" (see column 3, lines 9-11 of Preece) and not as "reservoirs" as alleged by the present Office Action.

Further, even if Preece describes its part 14 as a glass capillary tube, and the part 28 as a syringe, their structural connections and functionality are completely different. For Example Preece recites as follows:

> In use, cooling water is circulated through the glass jacket 16, and **cells suspended in tissue-culture fluid are passed through the capillary 14 from the disposable syringe 28 driven by the stepping motor 29. Each step triggers the pulse unit 36**, which gives a high voltage (approx. 8Kv) pulse of defined length, applied to the electrodes 18 immersed in the electrolyte 20 contained in end block chambers.
> (Preece, column 3, lines 20-28, **emphasis added**)

As can be seen from this description, one of skill in the art would agree that Preece's syringe 28, in contrast to the "pressure maintaining means" of claims 18 and 25, appears to contain "cells suspended in tissue-culture fluid" and Preece's "motor 29 stepping" appears to trigger voltage pulse generation. This is in contract to Applicants claimed embodiments of "electroporation apparatus" in independent claims 18 and 25 which are also described in Applicants' specification in FIGS. 3-15 and [0059]-[0078]. Furthermore, Applicants describe functionality and superior results of electroporation of cells using the devices such as those claimed in claims 18 and 25 and their dependents in sections described in the present published specification at least in [0079]-[0088] and [0089]-[0099]. These or similar results are not described by Preece in relation to the devices described therein.

One of skill in the art, upon review of Preece, would not be able to make the device of claims 18 and 25 and their dependents or achieve the results described therein, absent the

teachings of the present specification. In fact, Preece's device would not be able to obtain electroporation taught by Applicants' device.

The MPEP in §2121.01 and Federal Circuit jurisprudence are clear that "[T]he disclosure in an assertedly anticipating reference must provide an enabling disclosure of the desired subject matter; mere naming or description of the subject matter is insufficient, if it cannot be produced without undue experimentation. *Elan Pharm., Inc. v. **>Mayo Found. For Med. Educ. & Research<*, 346 F.3d 1051, 1054, 68 USPQ2d 1373, 1376 (Fed. Cir. 2003).

Furthermore, the law on anticipation is clear that all elements disclosed must also be "arranged as in claim." the Northern District of California has held that, "[a]nticipation cannot be proven by cobbling together disparate elements in a prior art reference." *Advanced Cardiovascular Sys. v. Scimed Life Sys.*, 63 F. Supp. 2d 1064, 1073 (N.D. Cal. 1999). The *Advanced Cardiovascular* court specifically rejected a similar attempt to demonstrate anticipation by combining elements from different embodiments of the prior art reference. *Id.* at 1072 n.6. To demonstrate anticipation, in *Net MoneyIN, Inc. v. Verisign*, Inc., 545 F.3d 1359, 1371 (Fed. Cir. 2008), the Federal Circuit held that "anticipation takes *more* than simply locating each element within the four corners of a single document" and that [b]ecause the hallmark of anticipation is prior invention, the prior art reference—in order to anticipate under 35 U.S.C. § 102—must not only disclose all elements of the claim within the four corners of the document, but must also disclose those elements "arranged as in the claim." *Id.*, 545 F.3d 1369, citing *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1548 (Fed.Cir. 1983).

Applicants respectfully submit that in the present case Preece fails to teach each and every element of the present claims arranged as claimed and functioning as claimed by the present claims.

Accordingly, Applicants respectfully submit that Preece fails to anticipate independent claims 18 and 25. Since dependent claims incorporate by reference the limitations of their independent claim, dependent claims 19-24, 27, 28 and 43, are also free from the anticipation rejections at least for analogous reasons. Accordingly, Applicants respectfully request withdrawal of the rejections under and allowance of all pending claims

Allowable Claims 26, 44 and 45:

Applicants thank the Examiner for indicating claims 26, 44 and 45 are allowable if they overcome the rejections of indefiniteness. As the indefiniteness rejections have been addressed in sections above and are believed to be overcome, Applicants respectfully request allowance of said claims.

CONCLUSION

Applicants have made an earnest effort to place their application in proper form for allowance. In view of the foregoing, Applicants respectfully request reconsideration of this application, and allowance of claims.

Prompt and favorable consideration of this Amendment and Response is respectfully requested. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned at (512) 721-3657.

Respectfully submitted,

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